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NOTICE OF ALLOWANCE AND FEE(S) DUE

23505

7590

04/09/2009

EXAMINER

CUTLIFF, YATE KAI RENE

ART UNIT

PAPER NUMBER

1621

DATE MAILED: 04/09/2009

CONLEY ROSE, P.C. David A. Rose P. O. BOX 3267 HOUSTON, TX 77253-3267

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,466	05/30/2007	Anthony Michael Chandler	1821-02600	1516

TITLE OF INVENTION: SOLVENT EXTRACTION OF LIPIDS SUCH AS ESSENTIAL FATTY ACIDS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	07/09/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

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I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

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III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for

maintenance fee notifications. Note: A certificate of mailing can only be used for domestic mailings of the CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. 23505 7590 04/09/2009 Certificate of Mailing or Transmission CONLEY ROSE, P.C. I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below. David A. Rose P. O. BOX 3267 HOUSTON, TX 77253-3267 (Depositor's name (Signature (Date APPLICATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. FILING DATE 10/597-466 05/30/2007 Anthony Michael Chandler 1821-02600 1516 TITLE OF INVENTION: SOLVENT EXTRACTION OF LIPIDS SUCH AS ESSENTIAL FATTY ACIDS APPLN. TYPE SMALL ENTITY ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional NO \$1510 \$300 \$0 \$1810 07/09/2009 **EXAMINER** ART UNIT CLASS-SUBCLASS CUTLIFF, YATE KAI RENE 1621 424-523000 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. or agents OR, alternatively, (2) the name of a single firm (having as a member a ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) 4a. The following fee(s) are submitted: 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) lssue Fee A check is enclosed. Publication Fee (No small entity discount permitted) Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number ______ (enclose an extra copy of this fo Advance Order - # of Copies _ (enclose an extra copy of this form). 5. Change in Entity Status (from status indicated above) a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ■ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office. Authorized Signature Date Typed or printed name Registration No. This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

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David A. Rose		ART UNIT	PAPER NUMBER	
P. O. BOX 3267 HOUSTON, TX 77253-3267			1621 DATE MAILED: 04/09/200	9

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)		
	10/597,466	CHANDLER ET AL.		
Notice of Allowability	Examiner	Art Unit		
	YATE' K. CUTLIFF	1621		
The MAILING DATE of this communication appear All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI	(OR REMAINS) CLOSED in this a or other appropriate communication IGHTS. This application is subject	pplication. If not included on will be mailed in due course. THIS		
1. This communication is responsive to <u>December 22, 2008.</u>				
2. \square The allowed claim(s) is/are $\underline{1,4 \text{ and } 6-11}$.				
 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some* c) None of the: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: 				
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.	IENT of this application.			
4. A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which give				
5. \square CORRECTED DRAWINGS (as "replacement sheets") must	st be submitted.			
(a) 🔲 including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached				
1) hereto or 2) to Paper No./Mail Date				
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date				
ldentifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t				
6. DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT				
Attachment(s) 1. ☑ Notice of References Cited (PTO-892) 2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 4. ☐ Examiner's Comment Regarding Requirement for Deposit	5. ☐ Notice of Informal 6. ☐ Interview Summar Paper No./Mail D 7. ☐ Examiner's Amen	ry (PTO-413), rate		
of Biological Material	9.			
/Yate' K. Cutliff/ Assistant Examiner Art Unit 1621				

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Reasons for Allowance

1. The following is an examiner's statement of reasons for allowance:

2. None of the prior art extraction process teach or suggest the solvent extraction process for the extraction of lipids and fatty acids from Perna Canaliculus solids, where the solvent is selected from the group consisting of acetone, hexane and ethyl acetate and the solvent is removed from a mixture of dissolved lipids and solvent by nanofiltration, then the remaining solvent is removed from the concentration formed by nanofiltration. The process obtains high levels of polyunsaturated fatty acids (PUFA) of C20:5 and C22:6, as depicted in Tables 1 and 2. The process is conducted at or below ambient temperature.

The closest prior art references are McFarlane (US 4,455,298), Beaudoin (US 6,800,299) and in Macrides (WO 97/09992).

In McFarlane ('298) the process takes the dry mussel extract (Seatone®) and extracts lipids with ethyl acetate without filtration; and the solvent is dried before evaporation which generally requires heat. In '298 there is no disclosure that there was a desire to obtain fatty acids.

Beaudoin ('299) is a solvent extraction process for marine animals, however, it is mainly used with krill (shrimp) and Calanus (a crustacean type species like krill), and fish. The process discloses that it can use acetone but preferably uses a two step extraction process where acetone is used to dehydrate the animal and ethyl acetate is used to extract the lipid. Additionally, the process of Beaudoin uses heat to remove all

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traces of the solvent. Beaudion's chromatography results do not show the amount of fatty acid obtained from their lipid extraction process.

Macrides ('992) is an extraction process that uses supercritical CO2. The extracts of the Applicant's claimed process were compared to the extracts of the process set out in Macrides (WO 97/09992) at Table 1 in the specification. The process of '992 is currently one of the more widely used processes to extract lipids from Perna Canaliculus. Further, the comparison test shows that for Marcides, the resulting lipid extract have a considerably lower percentage of the desired PUFA than the extract of the claimed process. Lastly, the extraction process of '992 is conducted at temperatures of 40°C which is above ambient temperature.

Examiner noted that maintaining the extraction temperature at ambient temperature or below is important and recognized in the art, because high temperatures would degrade the PUFA. (Applicant's [0010]). Further, '299 notes that high temperatures negatively alter the lipids. (page 2, lines 24-23).

Furthermore, none of the above references disclose the use of nanofiltration.

Prevost et al. is the only reference that suggests the use of nanofiltration in a process that extracts lipids from animals and plants. However, the filtration is conducted under extraction conditions which require considerable pressure to maintain gaseous propane (solvent) in a liquid from for use as the liquefied solvent. Further, pressurization of the solvent extract is needed to drive the nanofiltration process. (see column 9, lines 8-15).

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Modification of the process of '298 with pressurized nanofiltration would not yield a dried solvent extract as required by '298, before the evaporation process. It would only add to the cost of the extraction process of '298.

Kosuage et al. (US 4,801,453) describes Seatone® as powder of dried and ground mussel.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yaté K. Cutliff/ Patent Examiner Group Art Unit 1621 Technology Center 1600

> /Porfirio Nazario-Gonzalez/ Primary Examiner Art Unit 1621